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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Everson Luiz de Almelda Artifon

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STITES & HARBISON PLLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER

SCHMIDT, EMILY LOUISE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,614	ARTIFON ET AL.	
	Examiner	Art Unit	
	EMILY WACHTEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-13 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-13 and 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>August 8, 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on August 8, 2007 has been considered in its entirety.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. The external concentric tube attached to the manipulation component of the perforation tube is not clearly shown, and the external concentric tube comprising reinforcements and the reinforcements at the first and second extremities must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter. Portions of the specification still do not appear to be in proper idiomatic English see for example at least [0018] in the clean version of the specification. Further in [0024] in the clean version of the specification a measurement of 0.035" is given it is not clear what this is a measurement of.

Claim Objections

4. Claim 9 is objected to because of the following informalities: claim 9 recites -- and combination of both-- the Examiner believes this to be --and a combination of both--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 9-13, and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holsinger et al. (US 5,843,091) in view of Andrews et al. (US 6,482,178 B1) and Forsberg (US 6,635,047 B2).

With regard to claims 9, 19, and 21, Holsinger et al. teach a catheter comprising: (a) a concentric perforating tube (Fig. 6A member 204) attached to a manipulation component on a first extremity (Fig. 6A assembly 200) and to a needle on a second opposite extremity (Fig. 6A needle 204); (c) an external concentric tube (Fig. 6A tube 208) having a first extremity attached to the manipulation component of the perforation tube and a second opposite extremity; internally bearing the concentric perforation tube, the needle and the radiopaque mark component, and having an external manipulating component adjacent to the manipulation component of the perforation tube (Fig. 1A member 12A - shown but not labeled in Fig. 6A); (d) a retraction blockage component externally attached to the external concentric tube portion (Device can incorporate external locking mechanism as described in Col. 12 lines 53-65 and would be attached to the external concentric tube via the end of assembly 200), and (e) an Y-shaped connector linearly attached to the manipulating component of the perforating tube (Fig. 1A member 14 - shown but not labeled in Fig. 6). Holsinger et al. does not specifically teach a radiopaque mark component externally attached to the needle. However, Andrews et al. teach it is well known in the art to place a gold, biocompatible radiopaque element on the distal end of a device to make the element visible to the user (Fig. 1 component 19, Col. 2 lines 1-7). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a radiopaque mark component externally attached to the needle in the device of Holsinger et al. because Andrews et al. teach using radiopaque elements is well known and routine in the art

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for allow the user to visualize the device. Holsinger et al. does not disclose the external tube to have reinforcements. However, Forsberg teaches a catheter tube with metal and polymer reinforcement layer along its length which would necessarily include the extremities at either end (Col. 2 lines 58-67) and further that it is known in the art to reinforce catheters (Col. 1 lines 12-13). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to reinforce the catheter tube in the device of Holsinger et al. because Forsberg et al. teach it is beneficial for reinforcing a catheter and that such is well known in the art.

With regard to claim 10, needle 204 comprises a lumen (Col. 13 lines 5-9) and is capable of delivering a guiding line.

With regard to claim 11, assembly 200 can be attached via a luer lock as in member 314 of Figs. 8 and 9.

With regard to claim 12, Holsinger et al. teach a catheter substantially as claimed. Holsinger et al. does not disclose what the manipulation component is made out of or specifically that it is a thermoplastic polymer. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to make the manipulation component out of a thermoplastic polymer because Applicant has not disclosed that such a material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the manipulation component of Holsinger et al. made from a variety of materials because it provides the device with the needed dimensional stability.

With regard to claim 13, member 208 is necessarily made of a material that is composed and it facilitates the sliding of member 204 through it.

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With regard to claim 20, the device is used with an endoscope (Col. 8 line 5).

With regard to claims 22-24, see Col. 8 lines 1-41. Specifically, regarding claim 23, the device can be locked in an extended position for use (Col. 12 lines 53-65).

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holsinger et al. (US 5,843,091), Andrews et al. (US 6,482,178 B1), and Forsberg (US 6,635,047 B2) as applied to claim 9 above, and further in view of de Toledo et al. (US 5,785,689).

With regard to claim 16, Holsinger et al. teach a catheter substantially as claimed. Holsinger et al. does not disclose the external tube to be made of PTFE. However, de Toledo et al. teach using PTFE tubing for catheters because it can be easily advanced around bends and is impervious to and compatible with therapeutic and bodily fluids (Col. 4 lines 18-20). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an external tube made of PTFE in the device of Holsinger et al. because de Toledo et al. teach using PTFE tubing for catheters because it can be easily advanced around bends and is impervious to and compatible with therapeutic and bodily fluids.

8. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holsinger et al. (US 5,843,091), Andrews et al. (US 6,482,178 B1), and Forsberg (US 6,635,047 B2) as applied to claim 9 above, and further in view of Mickley (US 2003/0216693).

With regard to claims 17 and 18, Holsinger et al. teach a catheter substantially as claimed. Holsinger et al. does not disclose the needle to be made of steel or a rigidity enabling sharp bends. However, Mickley shows a stainless steel component which is capable of making

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sharp bends (Fig. 1 shaft 136, [0034]). It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to make the needle out of stainless steel because Applicant has not disclosed that such a material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with a needle of a variety of materials as illustrated by Mickley that steel is one of several suitable options and further, it is routine to use steel components in the body because of their biocompatibility. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the needle out of steel in the device of Holsinger et al. because steel is a known material used for its biocompatibility and further Mickley shows that steel materials are capable of making bends.

Response to Amendment

9. The amendments to the claims, drawings, and specification have been entered.

Response to Arguments

10. Applicant's arguments filed December 1, 2008 have been fully considered but they are not persuasive. With regard to Applicant's argument that the catheter of Holsinger et al. is not an external concentric tube, the Examiner maintains that the catheter of Holsinger et al. is a tube and is both external to and concentric to the inner tube. With regard to Applicant's argument that Holsinger et al. does not teach an external manipulating component, the Examiner maintains that the feature generally indicated at 12a is external to the device and capable of manipulation. With regard to Applicant's arguments regarding the recitation of the blockage component, the Examiner maintains that the recited features of Holsinger et al. meet the recited claim limitations,

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the claims does not recite any limitations as to how the blockage component may or may not be attached. With regard to Applicant's arguments regarding Fosberg, the Examiner maintains the combination as proper, it would be obvious to one of ordinary skill to provide support to the device, and providing such support to the entire length of the device would necessarily include providing reinforcement portions at both extremities.

Regarding the arguments with respect to the drawings, the reinforcement portions are not indicated in the drawings. Further, the Examiner maintains that it is not clear in the Figures as to how the external concentric tube is attached to the manipulation component of the perforation tube.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571) 270-3648.

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The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Wachtel/
Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767